

DOCKET No. 13131-0310 (44378-282108)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Cham et al.)
Serial No. 10/601,656) Art Unit: **1648**
Filed: **June 20, 2003**)
For: **A Method of Treating and Preventing**)
Infectious Diseases Via Creation of a Modified)
Particle With Immunogenic Properties)

DECLARATION OF DR. MOIZ KITABWALLA UNDER 37 C.F.R. §1.132

I, Moiz Kitabwalla, Ph.D., do hereby declare:

1. I am an expert in the field of virology. I am currently the Manager of Viral Programs at Lipid Sciences, Inc. (Pleasanton, CA). I earned a B.Sc. degree (*summa cum laude*) in 1995 at the University of Wisconsin-Eau Claire. I earned a Ph.D. degree in Molecular Biology in 2001 at the University of Wisconsin-Madison. My *curriculum vitae* is enclosed (Exhibit A). I published over 13 papers in the field of Virology and Immunology, including HIV and SIV research. The list of the publications is enclosed (Exhibit B).
2. As one of ordinary skill in the art, I declare that *in vitro* SIV models were acceptable in and/or before the year of 2002 for the purpose of assessing induction of immune response for immunodeficiency virus, including HIV.
3. I declare that in and/or before the year of 2002 one of ordinary skill in the art in the field of virology accepted *in vitro* simian immunodeficiency virus (SIV) models as

reasonably correlating with immunodeficiency virus infection in an animal or a human for the purpose of assessing induction of immune responses to immunodeficiency virus, including HIV.

5. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine, or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of any patent issuing on this application.

Moiz Kitabwala
Signature

Moiz Kitabwala
Name

April 6th, 2005
Date

MOIZ KITABWALLA
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Professional Profile

- Experienced Ph.D. with over nine years of extensive training (academia and industry) in virology, molecular biology, immunology, and biochemistry.
- An innovative, independent researcher highly appreciated by colleagues as an invaluable team contributor.
- Lead researcher, organized all aspects of HIV-1 vaccine pre-clinical trial involving cohorts of non-human primates.
- Highly motivated, analytical, with a reputation for being a catalyst in developing strong and successful collaborative relationships with colleagues in diverse areas of research.
- Excellent communication, organizational, and computer skills, with proven record of aiding N.I.H. funding for laboratories.
- Excellent technical writing skills.

Professional and Research Experience

Lipid Sciences, Inc: Pleasanton, CA. 2003-
Manager, Viral Programs.

Manager of HIV and Enveloped virus vaccine development Program/Laboratory Manager.

- Led a research team developing novel therapeutic HIV vaccines based on Lipid Sciences patented delipidation process (pre-clinical data manuscript submitted).
- Wrote protocols, manuscripts, and coordinated pre-clinical research on HIV vaccine development with collaborators at Johns Hopkins Medical School, and Emory University.
- Organized annual Viral Advisory Board (V.A.B.) meetings for Lipid Sciences. Had total confidence of the V.A.B.
- Established an oncology vaccine division at Lipid Sciences, to explore companies novel delipidation process in creating better cancer vaccines.-provisional patent application filed.
- Principal Investigator on a STTR grant awarded by the N.I.H. to study SARS vaccine development.
- Established novel assays for measuring reverse cholesterol transport and phospholipids for the cardiovascular platform at Lipid Sciences, Inc.

Dana-Farber Cancer Institute/Harvard Medical School; Boston, MA. 2001-2003
Post-Doctoral Fellow, Harvard Medical School, the Department of Cancer, Immunology, and AIDS.

Lead Researcher on the Project: Blocking Milk-Borne HIV Clade A Transmission.

- Tested the ability of neutralizing human monoclonal antibodies (nmAbs) in blocking mother-to-child HIV clade A transmission, via breast-milk, in sub-Saharan Africa.
- Conducted research on in vitro neutralization assays using primary HIV clade A isolates from East Africa, for their susceptibility to the nmAbs (published).
- Created a chimeric SHIV-A (SIV/HIV chimera) expressing the HIV clade A envelope, by replacing envelopes from molecular clones of SHIV. The novel SHIV-A readily infects rhesus macaque cells, providing an animal model for studying HIV clade A pathogenesis (manuscript in preparation).
- Preliminary research on cross-clade nmAb protection and SHIV-A led to an N.I.H. grant awarded to Dr. Ruth M. Ruprecht, advisor, Harvard Medical School.
- Developed a novel high throughput non-radioactive cytotoxic T-cell assay to replace the chromium release assay (manuscript and patent in preparation).
- Conducted preliminary siRNA/nmAb synergy therapy experiments. Subsequently, published an editorial on siRNA in the New England Journal of Medicine.
- Assisted colleagues in designing experiments to detect in vivo HIV protein-cellular protein interactions using fluorescence resonance emission transfer (FRET).

The Institute of Human Virology (Dr. Robert C. Gallo, Director);

Baltimore, MD. 2000-2001

Visiting Research Graduate Student

Conducted final thesis experiments, and thesis writing.

- Thesis project, "Chemokine regulation of viral pathogenesis" successfully demonstrated the novel utility of gamma chemokine lymphotactin (ltn) as a powerful mucosal adjuvant in HIV vaccines.

University of Wisconsin-Madison; Madison, WI. 1995-2000

Graduate student, Cellular and Molecular Biology Program

Conducted thesis research: Chemokine regulation of viral pathogenesis.

- Cloned, expressed, and purified the rhesus macaque homolog of the novel gamma chemokine lymphotactin (ltn) expressed in E.Coli and Pichia pastoris system.
- Biochemically characterized ltn activity by calcium flux activity and chemotaxis assay, as well as receptor/ligand binding assays.
- Designed in vivo experiments to show functional activity and chemotaxis of lymphocytes by showing ltn was capable of inducing delayed type hypersensitivity (DTH) responses in rhesus macaques.
- Preliminary data on the functional and biochemical characterization led to a N.I.H. R.O.1 grant awarded to thesis advisor, Dr. C.D. Pauza. Funding supported the thesis project, and led to novel recombinant attenuated SHIVs expressing ltn, RANTES, and MIP-1b.
- Created a highly sensitive novel ELISA to detect human and rhesus ltn, as well as Abs for intracellular ltn staining.

- Created several recombinant SHIVs expressing ltn, inactive ltn, and substantially assisted in creating SHIVs expressing b-chemokines RANTES, and MIP-1b.
- Showed in an in vivo vaccine/challenge model that ltn as well as RANTES could act as mucosal adjuvants in enhancing HIV vaccines (published).
- Thesis also contributed towards understanding the immunology of ltn by demonstrating that its expression had a strict requirement for T-cell receptor signalling (published).
- Set up a successful collaboration to elucidate the solution structure of ltn by NMR (published by Dr. Brian Volkman's laboratory). Assisted Dr. Volkman and his team in securing N.I.H. funding for the research.

Abbott Laboratory, Ashland, OH. 1995

Technician, Quality Control-Abbott Plastics and Rubber Division.

Quality control for rubber and plastics components made in the Ashland plant.

- Routinely used GC-mass spectroscopy and HPLC, to monitor quality of rubber and plastic consumables such as baby nipples.

Education**Ph.D. Molecular Biology**, University of Wisconsin-Madison, Cellular and Molecular Biology Program, Madison, WI. 2001

- Thesis project- Chemokine Regulation of Viral Pathogenesis- entailed testing the utility of chemokines as mucosal adjuvants for HIV vaccines
- Research involved a cohort of 24 non-human primates, and coordination of experimental protocols, assays, and schedules.

B.Sc. (Summa Cum Laude), Biochemistry/Molecular Biology, University of Wisconsin-Eau Claire, Eau Claire, WI. 1995

- Gained valuable research experience in virology by designing experiments to elucidate anti-TNF mechanisms developed by a human DNA virus, cytomegalovirus (CMV).

Professional Affiliations

American Association of Immunologists (AAI)-Member

The Federation of American Societies for Experimental Biology (FASEB)-Member

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1. **Moiz Kitabwalla**, Francois Villinger, Aftab A. Ansari, James E.K. Hildreth, Hassibullah Akeefe, Zhaohao Liao, Ann E. Mayne, Lisa Gargano, Adam P. Conner, Jo-Ann Maltais, Gretchen Kunas, and Marc Bellotti. Enhancement of cell mediated immune responses using lipid depleted lentivirus as immunogen: A novel approach for inducing recognition of new viral epitopes. Accepted. *Vaccine*.
2. Paul M. Waterman*, **Moiz Kitabwalla***, Glen S. Hatfield, Peter S. Evans, Yichen Lu, Ilia Tikhonov, Joseph M. Bryant, and C. David Pauza. Effects of virus burden and chemokine expression on immunity to SHIV in nonhuman primates. *Viral Immunology*. In Press. 2004
*Authors contributed equally to the research.
3. Jeffrey Safrit, Ruth Ruprecht, Flavia Ferrantelli, Weidong Xu, **Moiz Kitabwalla**, Koen Van Rompay, Marta Marthas, Nancy Haigwood, John Mascola, Katherine Lazuriaga, Samuel A. Jones, Bonnie J. Mathieson, and Marie-Louise Newell; Ghent IAS Working Group on HIV in women children. *Journal of Acquired Immune Deficiency Syndrome*. (2).pp169-77, 2004.
4. Flavia Ferrantelli, **Moiz Kitabwalla**, Robert A. Rasmussen, Chuanhai Cao, Ting-Chao Chou, Hermann Katinger, Gabriela Stiegler, Lisa A. Cavacini, Yun Bai, Joseph Cotropia, Kenneth E. Ugen, and Ruth M. Ruprecht. Potent cross-group neutralization of primary Human Immunodeficiency Virus isolates with Monoclonal antibodies-Implications for Acquired Immunodeficiency Syndrome vaccine. *Journal of Infectious Diseases*. (1).pp71-74, 2004.
5. Ruth M.Ruprecht, Flavia Ferrantelli, **Moiz Kitabwalla**, Weidong Xu, and Harold M.McClure. Antibody protection:Passive immunization of neonates against oral AIDS virus challenge. *Vaccine*. (21).pp3370-3373, 2003.
6. **Moiz Kitabwalla**, Flavia Ferrantelli, Tao Wang, Alistair Chalmers, Hermann Katinger, Gabriela Stiegler, Lisa A. Cavacini, Ting-Chao Chou, and Ruth M. Ruprecht. Primary African HIV Clade A and D Isolates: Effective Cross-Clade Neutralization with a Quadruple Combination of Human Monoclonal Antibodies Raised Against Clade B. *AIDS Research and Human Retroviruses*. (19), No:2.pp125-131, 2003.
7. Paul M. Waterman*, **Moiz Kitabwalla***, Ilia Tikhonov, and C. David Pauza. Simian/Human Immunodeficiency Virus89.6 Expressing the Chemokine Genes MIP-1 β , RANTES, or Lymphotactin. *Viral Immunology*. (16), No:1.pp35-44, 2003. *Authors contributed equally to the research.
8. **Moiz Kitabwalla**, and Ruth M. Ruprecht. RNA Interference: a new weapon against HIV and beyond. *New England Journal of Medicine*. (347), No:17.pp 1364-1367, 2002.

9. **Moiz Kitabwalla**, Tao Wang, Jeremy McKay, Julie Overbaugh, and Ruth M. Ruprecht. Construction and Characterization of a Replication Competent Simian/Human Immunodeficiency Virus (SHIV) Expressing the HIV-1 Clade A Envelope (SHIV-A). In Preparation.
10. **Moiz Kitabwalla**, Alistair Chalmers, Tao Wang, Robert Rasmussen, Shisong Jiang, Jeremy McKay, and Ruth M. Ruprecht. A high through-put assay that effectively replaces the classic ⁵¹chromium release assay for measuring CTL and ADCC activity. In Preparation.
11. **Moiz Kitabwalla**, Alistair Chalmers, Robert Rasmussen, Shisong Jiang, Tao Wang, Jeremy McKay, and Ruth M. Ruprecht. A novel method for measuring CTL and NK cell-mediated cytotoxicity against targets infected by viruses, using two-color flow cytometry. In Preparation.
12. Ilia Tikhonov, **Moiz Kitabwalla**, Miroslav Malkovsky, Marianne Wallace, and C. David Pauza. Staphylococcal superantigens induce lymphotactin production by human CD4+ and CD8+ T cells. *Cytokine*. (16), no: 2, pp73-78, 2001.
13. Sonay Kuloglu, D.R. McCaslin, **Moiz Kitabwalla**, C. David Pauza, John L. Markley, and Brian F. Volkman. Monomeric solution structure of the prototypical 'C' chemokine Lymphotactin. *Biochemistry* (40), no: 42, pp 12486-12496, 2001.
14. Marianne Wallace, Paul M. Waterman, Jacque L. Mitchem, Mahmoud Djavani, Charles Brown, Parul Trivedi, Douglas Horejsh, Marta Dykhuizen, **Moiz Kitabwalla**, and C. David Pauza. Lymphocyte activation during acute simian /human immunodeficiency virus SHIV_{89.6pd} infection in macaques. *Journal of Virology* (73), no:12, pp 10236-10244, 1999.
15. Daniel N. Streblow, **Moiz Kitabwalla**, Miroslav Malkovsky, and C. David Pauza. Cyclophilin A modulates processing of Human Immunodeficiency Virus type I p55 Gag: mechanism for antiviral effects of cyclosporin A. *Virology* (245), no:2, pp 197-202, 1998.
16. Daniel N. Streblow, **Moiz Kitabwalla**, and C. David Pauza. Gag protein from Human Immunodeficiency Virus type I assembles in the absence of Cyclophilin A. *Virology* (252), no:1, pp 228-234, 1998.
17. Cheryl L. Muller, Jason R. Bever, Mark S. Dordel, **Moiz Kitabwalla**, Theresa M. Reineke, Justin B. Sausker, Troy R. Seehafer, Yu Li, and Jerry Jasinski. Regiochemistry of Intramolecular photocycloaddition of 1,3-Dioxin-4-ones tethered through the ketal carbon. *Tetrahedron Letters* (50) no:38, pp 8663-8666, 1997.